UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA *EX REL.*	CIVIL ACTION NO. H-07-2705
JANE DOE	**FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**
PLAINTIFF,	
v.	JURY TRIAL DEMANDED
ENDOSCOPIC TECHNOLOGIES, INC.,	
DEFENDANT.	

COMPLAINT

Plaintiff and qui tam relator Jane Doe, through her attorneys Sanford, Wittels & Heisler, LLP, for her Complaint against Endoscopic Technologies Inc., Estech, (hereinafter "Defendant" or "Estech") alleges as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by the Defendant and/or its agents and employees in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq., ("the FCA" or "the Act").

2. This qui tam case is brought against Defendant for conducting a fraudulent marketing and inducement campaign that foreseeably caused false or fraudulent claims for procedures performed using Defendant's Cobra ablation products to be presented to the Medicare program. As a direct result of Defendant's improper practices, the Federal Treasury has been damaged in a

substantial amount yet to be determined.

3. Since the introduction of their Cobra ablation products, one of the largest obstacles Defendant has faced in selling their products is that their only use is for the off-label treatment of atrial fibrillation. Defendant initiated a coordinated nationwide sales campaign (including the use of illegal kickbacks and other improper means) to entice physicians and hospitals to use their products for off-label purposes.

4. For the majority of patients, cardiac ablation can be more safely performed, at a lower cost, as an outpatient procedure performed by an electrophysiologist ("EP") in a catheterization lab. EPs are specialized cardiologists. In a catheter ablation procedure, the patient is awake with less anesthesia (under conscious sedation), experiences fewer side effects, and will go home the same day of the procedure. Inpatient admission is not medically necessary. However, through their aggressive off-label marketing campaign, Defendants have induced hospitals to use their cardiac surgical ablation procedures, which are performed by cardiothoracic surgeons and billed as inpatient procedures.

5. Defendant has promoted its products to hospitals by highlighting the high spread between Medicare reimbursement for procedures performed with Defendant's products and the relatively low cost of those procedures. Defendant has encouraged cardiothoracic surgeons to perform procedures using Defendant's products as a means of winning business for those surgeons.

6. Defendant has done more than just talk to physicians and hospitals about off-label uses for Defendant's products. In order to bolster this off-label marketing campaign, Defendant has given both hospitals and physicians kickbacks and other inducements to encourage them to buy and use Defendant's Cobra ablation products.

7. Defendant's sales representatives also provide free equipment to hospitals to induce them to purchase a specified quantity of Defendant's products. Free equipment, in effect, increases the hospital's reimbursement for the procedure as it reduces hospital costs. By increasing the hospital's revenues, providing free equipment creates an additional inducement to perform an increased number of surgical ablation procedures.

8. Defendant also offers price discounts to induce hospitals to "lock-in" to a market share commitment to buy Defendant's cardiac ablation products. When entering into these agreements, the hospitals agree to allow Defendant to confiscate all competitors' products and equipment from the hospital vicinity to ensure that the hospitals will use only Defendant's products. These market-share commitments interfere with the discretion of the physicians to use the treatment that is in the best interest of each particular patient.

9. Defendant also provides cardiothoracic surgeons free advertising and referral services in exchange for the surgeon's agreement to use Defendant's products. Such services are particularly valuable to those surgeons because, in recent years, they have been faced with declining case volumes due to of the rise of catheter-based, outpatient procedures used by EPs, cardiologists, to treat cardiac illnesses. Defendant thus pitches their products (and the attendant procedures) to cardiothoracic surgeons as a way to win back market share (i.e., by giving cardiothoracic surgeons a "cutting edge" new surgical treatment that only they can offer to patients).

10. Recognizing this market opportunity (i.e., that cardiothoracic surgeons were losing market share), Defendant offered the surgeons kickbacks in the form of free advertising, press, and referral services to bring in more patients and business to the surgeons and to promote the surgeons as eminent physicians that provide this new cutting edge procedure. This in-kind marketing support

by sales representatives includes marketing to other physicians (i.e., primary care physicians, family practitioners) who can directly refer those newly diagnosed atrial fibrillation patients to the cardiothoracic surgeons for surgery as a treatment option, thus eliminating the cardiologist, whose normal protocol for the treatment of atrial fibrillation is drug therapy and catheter ablation -- all done as outpatient procedures. By changing the normal course of referral patterns and replacing the referral to a cardiologist with direct referral to the cardiothoracic surgeon, the patient can then be referred for surgical ablation as a first line therapy instead of the outpatient therapy option that a cardiologist would provide for that same patient. These referral services provide an extremely valuable benefit for the surgeons in marketing their practice. This marketing support also promotes performance of additional surgical ablation procedures and the purchase of more of Defendant's products.

11. The decline of cardiothoracic surgery has also caused many cardiothoracic surgeons to seek training for new treatments. Another in-kind benefit Defendant provides to physicians is direct, extensive training by sales representatives and "ablation account managers" to teach the surgeons how to perform surgical ablation for the off-label treatment of atrial fibrillation. In order to obtain this training, hospitals or physicians must agree to lock-in to an agreement to purchase and utilize Defendant's products.

12. As a result of Defendant's off-label marketing and illegal kickbacks campaign, a substantial number of patients have undergone more intensive, inpatient surgical ablation procedures, where less intensive, outpatient catheter ablation procedures (or other treatments) should have been performed instead. The Medicare program has faced substantial increased costs for these inappropriate inpatient surgical procedures.

13. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

14. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

15. The Act allows any person having information about false or fraudulent claims to bring an action for herself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, qui tam plaintiff and relator Jane Doe seeks through this action to recover damages and civil penalties arising from the Defendant's knowing fraud on the U.S. Government.

II. PARTIES

16. Jane Doe is a resident of **[REDACTED]**. Ms. Doe was employed by Boston Scientific from **[REDACTED]** as a Sales Representative in the **[REDACTED]** region and worked in

both **[REDACTED]** and **[REDACTED]**. As a former sales representative that was trained to market ablation products for the treatment of atrial fibrillation, Ms. Doe has specialized knowledge of industry-wide practices, including the improper billing and coding practices at Estech.

17. Defendant Endoscopic Technologies, Inc., is headquartered in San Ramon, CA. Estech is a privately held company that develops, manufactures, and markets medical devices. Estech specializes in developing the "least invasive products for cardiac surgery." Estech markets the Cobra ablation system, which uses radiofrequency energy to create lesion sets for the treatment of atrial fibrillation.

III. JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

19. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendant has at least minimum contacts with the United States. Moreover, the Defendant can be found in and transacts – or has transacted – business in the Southern District of Texas.

20. Venue is proper in this District pursuant to 31 U.S.C. §3732(a), because the Defendant can be found in and transacts – or has transacted – business in the Southern District of Texas.

IV. BACKGROUND

A. THE MEDICARE PROGRAM

21. Medicare is a federally funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

22. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests, and other medical services not covered by Part A.

23. The Centers for Medicare and Medicaid Services (CMS) administers Medicare, but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying claims for reimbursements under Medicare Part B

1. Medicare Payments to Hospitals

24. Medicare pays hospitals different amounts for various services based, in part, on the setting (e.g., inpatient or outpatient) where the services were performed. Hospitals are generally reimbursed for inpatient services on a "per case" basis. In other words, each inpatient hospitalization is assigned a Diagnosis Related Group ("DRG") based on the nature and severity of the patient's diagnosis and the services performed. Medicare then pays the hospital a pre-determined reimbursement rate based on the DRG. The pre-determined DRG reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided.

25. DRGs are assigned to a case through a process called "grouping." A "grouper" is a type of software that reviews various data related to the hospitalization (especially the patient's diagnosis and the procedures performed) to determine the appropriate DRG for the treatment.

26. In most cases, the procedure performed by the hospital is one of the most significant, if not the determinative, data point affecting the DRG grouper's decision. These procedures are classified and reported using International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system, established by CMS and the National Center for Health Statistics. These codes are commonly referred to as "ICD-9 procedure codes."

27. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed, including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

2. Medicare Payments to Physicians

28. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately from the hospital's DRG or APC payment.

29. Like hospital reimbursement, Medicare bases physician reimbursement on the assumption that similar types of procedures consume a similar amount of resources, and thus deserve similar reimbursement. Accordingly, Medicare reimburses physicians based on standardized procedure codes – HCPCS and CPT codes, as described below.

30. Each procedure code is assigned a weight or value (called a Resource Based Relative Value Unit or "RBRVU"), as determined by the Resource-Based Relative Value Scale ("RBRVS").

The payment level for any given procedure is then determined by multiplying the RBRVU value for the code times a conversion factor (which takes into account regional and other variable cost factors).

31. The RBRVS system is based on the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid, and other federal health care programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to standardized codes.

32. Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA").

33. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Radiology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

34. The instructions that accompany the CPT manual direct providers "not [to] select a CPT code that merely approximates the service provided." Rather, when none of the standard CPT codes provides an accurate description of the services provided or procedure performed, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e., the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describe the specific procedure or service provided).

35. Codes listed after each subsection in the CPT Manual and ending in -99 are "unlisted" codes. When a provider submits a claim with a "99" code, he or she must also provide supplemental information describing the procedure performed so that the carrier may determine the appropriate reimbursement. Correct code assignment occurs after this extra documentation for the claim is reviewed by the carrier

36. Physicians typically submit claims for professional services on Form CMS-1500. The claim form sets forth the diagnostic code describing the patient's presenting condition and the procedure codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient ...."

3. Other Rules Governing Payments to Both Hospitals and Physicians

37. In addition to compliance with other national or local coverage criteria, Medicare requires, as a condition of coverage, that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services and, then, provide such services only where medically necessary. 42 U.S.C. § 1320c-(a)(1). Providers must provide evidence that the service is medically necessary and appropriate. 42 U.S.C. § 1320c-5(a)(3). Providers must ensure that services provided are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6)&(8).

38. Federal law also specifically prohibits providers from making "any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program." See 42 U.S.C. § 1320-a-7b(a)(1). Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to the Medicare to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be

truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

39. It is unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship. See 42 U.S.C. §1395nn(a)(1).

B. THE ANTI-KICKBACK STATUTE

40. The federal health care Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, are of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

41. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has, as one of its purposes, inducement of a physician to perform additional procedures using the company's products.

42. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

43. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider in federal health care programs. Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

44. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services ("HHS") finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant state agency(ies) to exclude that provider from the state health program), and may consider imposing administrative sanctions of $50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

C. TREATMENT OF ATRIAL FIBRILLATION, WITH AND WITHOUT ABLATION

45. Atrial fibrillation is a very fast and irregular beating of the atria. Atrial fibrillation is the most prevalent type of arrhythmia leading to hospital admission. Over 2.2 million Americans suffer from atrial fibrillation, and approximately 160,000 new cases are diagnosed every year.

1. Treatment of Atrial Fibrillation Without Ablation

46. Treatment with antiarrhythmic drugs and anticoagulation is considered first-line therapy in patients with symptomatic atrial fibrillation.

47. The cardiac "maze" procedure is a form of open-heart surgery used to treat atrial fibrillation with strategic placement of incisions in both atria. Since its introduction, the maze procedure has undergone three iterations: Maze I, II, and III, which all involve cut and sew techniques used during open-heart procedures. Despite its high success rate, the maze operation has not been widely adopted except for patients undergoing cardiac surgery because of the need for cardiopulmonary bypass, the morbidity and complication rates, and because it is a very challenging procedure for the surgeon to perform.

2. Treatment of Atrial Fibrillation with Ablation

48. In recent years, physicians have begun to try to treat atrial fibrillation by ablating – i.e., removing or destroying – certain heart tissue with various forms of energy (e.g., radio frequency, microwave). In general, physicians have experimented with two types of ablation procedures: (1) catheter ablation and (2) surgical ablation.

a. Catheter Ablation

49. Catheter ablation is a minimally invasive procedure that involves the use of a catheter that is threaded through the leg and into the heart. The catheter is equipped with a device that delivers radiofrequency waves to the arrhythmia source.

50. Catheter ablation is an outpatient procedure performed by an electrophysiologist ("EP") in a catheterization lab. EPs are specialized cardiologists. In a catheter ablation procedure, the patient is generally awake with less anesthesia (under conscious sedation) or in some cases under general anesthesia, experiences fewer side effects, and will go home within one day of the procedure.

51. Catheter ablation has recently gained recognition as an effective procedure to treat atrial fibrillation. A large number of studies have reported high rates of successful treatment and a low incidence of complications with the catheter ablation techniques.

52. The American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, and the European Society of Cardiology Committee for Practice are the premier medical societies that establish "standards of care" and treatment protocols for patients with cardiac conditions. In 2006, the Guidelines for patients with atrial fibrillation were updated to include catheter-based ablation as a third-tier treatment option, following drug therapy and cardioversion. This is the first time catheter-based ablation was included as a standard of care, because, until this time, catheter-based ablation had been considered experimental. Catheter-based ablation has been used in practice for a much longer period of time (around 5 years) than surgical ablation, which is why surgical ablation is still considered experimental, and was not added to the recommended practices, or considered a "standard of care".

b. Surgical Ablation

53. Surgical ablation is a surgical procedure performed in the operating room with the patient under general anesthesia. The procedure is a derivative of the maze procedure using radio frequency (or other) energy to create lesions, rather than a cut and sew technique.

54. Surgical ablation procedures are generally performed by cardiothoracic surgeons. Unlike catheter ablation procedures, which are performed on an outpatient basis, surgical ablation procedures are generally performed on an inpatient basis, requiring the patient to stay in the hospital.

55. There is not yet an efficacy study assessing the safety and efficacy of using radio frequency surgical ablation or any other energy source to perform surgical ablation for the treatment

of atrial fibrillation.

56. Surgical ablation may be performed as either an open-heart procedure (often in conjunction with another open-heart procedure) or as a "minimally invasive" procedure.

57. A wide variety of minimally invasive forms of surgical ablation, including thoracoscopic epicardial ablation, are currently being investigated as potential forms of treatment for atrial fibrillation. Because the efficacy and safety of thoracoscopic surgical ablation are still under investigation, the procedure is considered more experimental and is less accepted than either catheter ablation or the maze surgical procedure.

58. At the AATS (American Association of Thoracic Surgeons) Society meeting in May, 2007, several surgeons, including Dr. J. Crayton Pruit, reported that efficacy rate of surgical ablation was lower than 50% in clinical studies.

59. The Heart Rhythm Society (HRS), European Hearth Rhythm Association (EHRA), and European Cardiac Arrhythmia Society (ECAS) have recently released their Expert Consensus Statement regarding surgical ablation for atrial fibrillation (AF). The Expert Consensus Statement set forth that "prospective multicenter clinical trials are needed to better define the relative safety and efficacy of surgical [ablation] tools and techniques." The Statement also revealed that "[t]he true success rates of these procedures are likely to be lower than has been reported."

60. A stand-alone, minimally invasive surgical ablation procedure – unlike traditional heart surgery – does not require opening the thoracic cavity to expose the heart and lungs and does not require putting the patient on a heart-lung bypass machine to stop the heart. Patients treated with the minimally invasive, closed-chest procedure generally recover faster than those treated with procedures that require open heart access.

c. Surgical Ablation with Defendant's Cobra Surgical Ablation System

61. Defendant's Cobra ablation system consists of a radio-frequency power generator known as an electrosurgical sensing unit ("ESU"), which uses radiofrequency energy to heat tissue and is used in conjunction with surgical probes to create lesion sets for the treatment of atrial fibrillation. The Bipolar RF Ablation Clamp is used to isolate the pulmonary veins, and the Cobra Adhere Ablation System is used to connect lesions while surgeons place a suction stabilizer that on the epicardial surface of the heart while the heart is beating. The Bipolar Pacing Probe ("AFFirm") is used to evaluate the effectiveness of ablation in treating atrial fibrillation by verifying the conduction block of abnormal electrical pathways in the heart.

62. Defendant's Cobra ablation system can be used either in conjunction with open heart surgery or as a stand-alone minimally invasive procedure.

63. Defendant's product, the Cobra XL is marketed for the minimally invasive stand-alone use of ablation to treat atrial fibrillation.

64. A stand-alone minimally invasive procedure, unlike traditional heart surgery, does not require opening the thoracic cavity to expose the heart and lungs and does not require a heart-lung machine. An Estech press release, dated September 23, 3005, describes that the minimally invasive technique "involves making a simple incision in the chest and inserting two different radiofrequency (RF) ablation devices into the area behind the heart."

D. MEDICARE COVERAGE OF ABLATION PROCEDURES

65. Typically, catheter ablation and surgical ablation are recommended as treatment for atrial fibrillation only when the patient is either intolerant of or resistant to drug therapy.

66. There is no National Coverage Determination for reimbursement for radio frequency surgical ablation. Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation.

67. Defendant has directed substantial effort to obtain coverage for radio frequency surgical cardiac ablation procedures through the Medicare Carriers.

68. As alleged herein, Defendant developed a marketing scheme to exploit high reimbursement under DRG 108 for the stand-alone surgical ablation procedure using their product to persuade hospitals to purchase their products. Under DRG 108, hospitals obtain an average reimbursement of $30,289. Because the average total cost to the hospital for use of Defendant's stand-alone, minimally invasive products is only $10,650, hospitals make a substantial profit whenever such a procedure is performed. Defendant heavily promotes this fact as part of their campaign to get hospitals to perform surgical ablation procedures using Defendant's products.

69. Defendant also coaches hospitals to "upcode" the minimally invasive, closed-chest, procedure to a procedure code for open-heart DRG 108 to take advantage of the Medicare care system and obtain an over-reimbursement of approximately $20,000 per a procedure.

V. ALLEGATIONS

A. DEFENDANT ILLEGALLY MARKETS ITS PRODUCTS TO HOSPITALS AND PHYSICIANS

70. Since 2001, Defendant has aggressively marketed their surgical ablation products to induce hospitals and physicians to purchase their products and use them specifically (and only) for off-label treatment of atrial fibrillation.

71. In large part due to that aggressive and improper off-label marketing campaign, Defendant's surgical ablation product has been used to treat atrial fibrillation in more than 1,600 stand-alone, closed-chest, thoracoscopic ablation procedures and in approximately 15,000

concomitant procedures (i.e., open-heart ablation procedures done in conjunction with another open-heart procedure).

72. Since approximately 2003, Defendant devised a strategy to further expand such off-label use of their product. This strategy involves marketing their minimally invasive, stand-alone products by advising hospitals to take advantage of the Medicare system to obtain over-reimbursement for such procedures.

1. Defendant Aggressively (and Exclusively) Promotes Their Product for Off-label Treatment of Atrial Fibrillation

73. Although Defendant's surgical ablation system is not FDA-approved for the treatment of atrial fibrillation, Defendant specifically markets it for that use. In fact, that is the only practical, cost-effective use for their product and the only use for the product that Defendant promotes.

74. Defendant's surgical ablation system is categorized as a Class II device, which, pursuant to 42 C.F.R. 405.201, "require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness."

75. The indicated use of surgical ablation that was approved by the FDA in Defendant's 510(k) premarket notification was for *general use* "for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery." The system can "be used during general surgery to coagulate soft tissues" and "to coagulate blood and soft tissue to produce hemostasis." The device may also be used "to remove tissue and control bleeding by use of high-frequency electrical current." *See* 21 C.F.R. 878.4400.

76. When a device is approved by the FDA for a general use, a specific indication for use can become a new intended use that requires submission of an additional 510(k) approval to establish the safety and effectiveness of the device.

77. The FDA has determined that the use of Defendant's product to treat atrial fibrillation

is a specific indication for a new intended use, which requires an additional pre-market approval, due to considerations of safety and effectiveness.

78. There is not yet an efficacy study assessing the safety and efficacy of using Defendant's product to treat atrial fibrillation.

79. Defendant has not received FDA clearance or 510(k) approval supporting the specific use of surgical ablation to treat atrial fibrillation.

80. The FDA has denied specific approval for the use of surgical ablation to treat atrial fibrillation three times.

81. Notwithstanding the absence of specific approval, the only real-world, actual use of Defendant's surgical ablation system is to treat atrial fibrillation.

82. Thus, all current uses of the Cobra surgical ablation system are off-label. Moreover, the underlying purpose of all of Defendant's training and marketing of their ablation system is to promote the off-label treatment of atrial fibrillation.

83. All of Defendant's sales activities, including promotion of high reimbursements, upcoding, kickbacks such as free products, free advertising, and referrals, are for the off-label promotion of Defendant's products to treat atrial fibrillation, which is experimental and not approved by the FDA.

84. Defendant falsely misbrands and markets its AFFirm conduction block probe as having received FDA "[approval] for use in the treatment of Atrial Fibrillation." The training manual instructions to representatives explain that they should promote the probe as having received FDA approval for the treatment of atrial fibrillation: "What makes [AFFirm] so special is that it IS: THE ONLY TECHNOLOGY TO HAVE AN FDA INDICATION FOR THE TREATMENT OF AF."

85. Defendant's Cobra Adhere XL is promoted off-label as a device with an FDA indication for minimally invasive, closed chest procedures. Defendant promotes the Cobra Adhere XL as "a minimally invasive technique to treat [atrial fibrillation]"). In the 510(k) documents, the FDA describes the Cobra surgical system as "intended for use by surgeons for the coagulation of cardiac and soft tissues *during open surgical procedures*." The Defendant is thus wrongfully promoting its Adhere XL product as indicated for minimally invasive, closed chest procedures.

86. Defendant's sales representatives also promote the off-label use of Defendant's product by directly training doctors to use Defendant's ablation system to treat atrial fibrillation.

87. Defendant's sales representatives were not taught to treat any condition other than atrial fibrillation with Defendant's product.

2. Defendant "Markets the Spread" – Emphasizing the High Reimbursement to Cost Ratio for Off-label Use of Its Product – As Part of Its Aggressive Off-Label Pitch to Hospitals

88. Defendant aggressively promotes the off-label use of their product by hospitals by "marketing the spread" between the high DRG reimbursement for atrial fibrillation procedures using their products and the low cost of those procedures. (The details of Defendant's "marketing the spread" scheme are somewhat different from the practice as executed in the pharmaceutical industry, because Defendant does not have the same level of control over the reimbursement for their products as pharmaceutical companies do. In this case, however, Defendant's conduct has the same practical effect – namely, encouraging hospitals to purchase their product simply because of the high profit margin that the hospital will realize. Moreover, Defendant's aggressive promotion of the high profit margin hospitals can expect to see when Defendant's products are used to treat atrial fibrillation demonstrate that Defendant is aggressively promoting the use of their product for that one specific off-label use. Defendant also offers hospitals kickbacks and volume discounts that effectively

reduce hospital costs and increase the hospitals' profit margins when they use Defendant's inpatient procedures).

89. Defendant's promotional literature and sales presentations to hospitals emphasize favorable reimbursement from Medicare as the central marketing theme used to induce hospitals and surgeons to purchase and use their products off label.

90. In using reimbursement pitches in their sales presentations, Defendant explained, "Two parties are interested in reimbursement : 1) Surgeons and 2) Hospitals." Defendant further depicted that surgeons were interested in reimbursement because "Dx + Procedure = $" and hospitals are interested because "procedure = DRG = $." Thus, Defendant clearly expected that the financial gain to surgeons and hospitals would propel their sales and used this financial gain in their marketing pitches.

91. Defendant's sales representatives are instructed to promote the use of Defendant's bipolar ablation system to treat atrial fibrillation by advising hospitals and doctors that they can obtain substantially higher reimbursements from Medicare by using their products. In its promotion of its products to hospitals, Defendant asks rhetorically "Can Treatment for [atrial fibrillation] be profitable for Lancaster Hospital?" Defendant responds that Lancaster Hospital can generate $1,302,427 in new revenues per a year if it attracts 44 new atrial fibrillation patients through Defendant's outreach program. This number is calculated by multiplying the amount of reimbursement from DRG 108 by 44. Additionally, Defendant promoted the AF Outreach Program to Lancaster General Hospital by presenting that new revenue totaling $636,069/Year could be generated by identifying 20 Existing patients who are already in the hospital system undergoing CABG procedures.

92. Defendant presented its atrial fibrillation procedure to Osceola Regional Hospital as a source of profit. Defendant stressed that the new revenue generated from treating atrial fibrillation in the existing CABG population base was $113,862 per year.

93. Estech's hired staff of medical professionals are required to accompany new surgeons into the operating room to provide the new surgeons with detailed instructions regarding how they can administer Defendant's product to treat Medicare patients with atrial fibrillation.

94. Estech also provides free advertising services for surgeons that promote its procedure by paying for the design, publication, and marketing of brochures, including camera-ready art work, that advertise the surgeon's name and explain that the surgeon treats atrial fibrillation by using Defendant's ablation system.

3. Defendant Provides Improper Remuneration (Kickbacks) to Physicians and Hospitals to Induce Them to Purchase, Perform and Use Its Products for Off-label Procedures

95. As set forth below, Defendant routinely provides illegal kickbacks to physicians to induce them to perform procedures using Defendant's products, and to hospitals to induce them to buy Defendant's products and to promote their use by physicians who practice at the hospital.

96. Because compliance with the anti-Kickback statutes is a condition of payment, claims for reimbursement for procedures performed by a physician who has received a kickback or at a hospital that has received a kickback from Defendant is not eligible for reimbursement by Medicare.

97. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

a. Defendant Provides Improper Kickbacks, in the Form of Free Marketing and Promotional Services, to Physicians to Induce Them to Perform Procedures Using Defendant's Products

98. Defendant provides physicians with tangible and in-kind services to induce performance of procedure and sales of its product. Some of the valuable in-kind services provided include marketing, advertising, and referral services.

99. Defendant's marketing campaign specifically targeted cardiothoracic surgeons, who, in recent years, have been losing business because of the increasing popularity of outpatient catheter ablation procedures. Defendant promoted surgical ablation procedures as a marketing tool for cardiothoracic surgeons – i.e., telling the surgeons that they could advertise their proficiency in this cutting edge, high profile new treatment for atrial fibrillation.

100. As part of this effort – and in recognition of the cardiothoracic surgeons' need to promote themselves to counter the rise of catheter-based treatment options – Defendant provides both marketing assistance and referral services to cardiothoracic surgeons when they agree to perform procedures using Defendant's product. These services are valuable, and thus constitute remuneration for purposes of the Anti-Kickback Statute.

101. For example, Defendant's training manual instructs sales representatives to conduct an "[Atrial Fibrillation] Outreach Program" to build the surgeon's practice "by bringing patients and *profit* to the hospital." Defendant's promotional materials regarding the AF Outreach program ask: "Are there patients in your community living with AF? Do they have to?" This AF Outreach program offers "AValue-added marketing program with an evidenced based solution: Estech reaches out to the underserved AF patient populations, teaches patients that there is a surgical option available, and delivers new patients into the hospital's network." Estech states that its "AF Outreach is a service designed to provide hospitals, health care organizations, and practitioners with the strategy, tools, and clinical training necessary to effectively market the cardiac surgical ablation solution." The piece goes on to teach hospitals ways to differentiate their services by offering

"advanced treatment for AF." It states "Reimbursement for Cardiac Ablation has increased 18% over the past year." It introduces hospitals to the "Direct-to-Patient Marketing Program: Targeted advertising campaign, customized press kit, and 'Call Center' patient tracking for AF."

102. Estech's AF Outreach Program Seminars are designed to bring new patients into a hospital's practice. The program provides for 40 "qualified attendees" per seminar (of which 6 new patients per seminar go in for treatment) with 4 seminars per year. Estech estimates a resulting 24 new patients a year, with eight new concomitant CABG patients, 16 new patients as candidates for the stand-alone minimally invasive procedure and $666,358 in new revenue generated for the hospital. Additionally, Estech advertises that its AF Outreach Program will attract 44 new patients, totaling 1,302,427 a year.

103. The AF Outreach Program provides participating hospitals and surgeons with the following additional marketing and promotional support materials: Print Ads (Color or Black & White, sizable), AF Patient Brochures, Allied Health Physicians Manual on Atrial Fibrillation (for Primary Care Physicians), Referral Physician Lecture (PPT), Community Lecture on Atrial Fibrillation (PPT), Planning & Delivering Community Lecture, Call Center Services, On-site Proctoring, and Preceptorship Training.

104. Defendant represents that the following products will be provided to hospitals as part of the AF Outreach Program: 12 disposable ablation devices, 3 COBRA, 3 COBRA Bipolar, 3 COBRA Adhere, 3 COBRA Adhere XL, 2 ESU Cables, 1 Loaner ESU – RF Generator (Estech standard 1 year agreement) and 1 Loaner Medela Vacuum Pump (Estech standard 1 year agreement).

105. Estech requires hospitals to "lock-in" an investment under two options to participate in the AF Outreach Program. The hospital must either: (1) pay $75,000 upfront in order to obtain Estech Surgical Ablation Equipment, or (2) pay an order amount of $150,000, which can be

amortized, with two shipments. Estech promotes to hospitals that: "Small investments can pay enormous dividends for Hospitals and Surgeons participating in the AF Outreach Program."

106. Estech's "Pathway of Care" program is used to identify patients, pull them through the system, and get them into the operating room to be treated. Estech enrolls patients in AF educational seminars; provides full training for surgeons and staff on AF surgical procedure; works with hospital staff to identify missed AF patients already in the system (potential surgical candidates).

107. Estech provides a "call center" to qualify and identify potential surgical patients and encourage them to attend informative seminars on atrial fibrillation. The company provides seminar registration (attendance tracking for patients), local and toll-free phone numbers, a "tracking and follow up" procedure for patients, and a database for patients. All of these services are provided to hospitals who participate in Estech's Outreach Program. Estech financially supports all of the program initiatives.

108. Estech's Outreach Program is an attempt to change the standard of care treatment protocols for this patient population and allow for patients to have access to surgery as a first line therapy. This strategy also allows surgeons to treat a primary patient pool for the condition of atrial fibrillation, rather than having cardiologists treat this patient population first, which would eliminate the vast majority of patients being referred for surgery as a treatment option. Cardiologists have access to drug therapy, catheter-based ablation, cardioversion, and pacemakers – all performed as outpatient procedures in catheter labs by cardiologists and electrophysiologists in an attempt to treat atrial fibrillation. By encouraging the primary care physicians and family practitioners to refer directly to the cardiothoracic surgeons, Defendant is encouraging the creation of a new referral

pattern in which the cardiothoracic surgeons are gaining an entirely new area of practice and hospitals are benefiting financially.

109. Similarly, Defendant directly drums up potential candidates for surgical ablation, and refers those potential patients to cardiothoracic surgeons who have agreed to use Defendant's product. Defendant sponsors "town hall" meetings and community symposiums to screen for patients who are good candidates for their surgical ablation procedures. Defendant then refers these screened patients to cardiothoracic surgeons who perform their surgical ablation procedures.

110. Defendant also helps cardiothoracic surgeons who have agreed to use its product to increase their patient pool by providing free advertising services. Defendant pays for the design, publication, and marketing of brochures – including camera-ready art work – that advertise the surgeon's name, promote the surgeon as an excellent physician, and explain that the surgeon treats atrial fibrillation by using Defendant's surgical ablation system.

111. Defendant also provides grants to surgeons who promote the procedure performed with their product. These grants are used to fund the training of new surgeons to use Defendant's product to treat atrial fibrillation.

112. Estech also promotes the use of its products by directly training doctors to use its ablation system. Estech's Training Manual describes, under the heading "Physician Training," that the AF Outreach Program has "on-site proctoring" with experienced surgeons, perfusionists, and scrub nurses that accompany new surgeons into the operating room to assist in conducting the ablation procedure.

b. Defendant Provides Free Equipment and Special Discounts to Hospitals to Induce Them to Purchase Defendant's Products, and to Discourage the Use of Competitor's Products

113. Defendant routinely provides kickbacks to hospitals in the form of free products or the free use of equipment, disguised in the form of discounts or equipment loans. Often these improper inducements are given on the explicit condition that the hospital will predominantly (or exclusively) use Defendant's products.

114. Defendant routinely provides hospitals with free products, including: (a) generators used to power Defendant's disposable equipment, worth approximately $28,000; and (b) disposable equipment used to perform surgical ablations, such as scopes, trays, and bovie cords. These gifts are given in exchange for the hospital's agreement not only to buy a targeted volume of Defendant's products, but also to give Defendant's products preferred status.

115. By receiving free products, hospitals reduce costs and increase reimbursement on each procedure performed. Because the DRG-based reimbursement to the hospital is fixed, the hospital pockets 100% of these "discounts."

116. Although these free gifts are often described in the contracts and invoices as simply "discounted" items, they do not comply with the Medicare anti-kickback safe harbor for legitimate discounts.

117. Furthermore, these "discount" arrangements with hospitals routinely require the hospitals to ensure that Defendant's products are used in a certain percentage (often 80% or more) of all surgical ablation procedures performed at the hospital. In such cases, any offered discounts are explicitly conditioned on the hospital's commitment to "lock in" a certain market share for Defendant's products.

118. Often, as part of these "lock in" arrangements, Defendant requires the hospitals to turn over to Defendant all competitors' products and equipment from the hospital vicinity to ensure that the hospitals will use only Defendant's products. In some cases, Defendant's sales

representatives disable the generators used to power the competitor's products (e.g., by taking the power cords and adaptors) to ensure that the hospital does not allow surgeons to use those competitor's products during surgical ablation.

119. Defendant also offers bundling incentives to hospitals such that if a hospital buys three scopes, it will get one scope for free.

120. Defendant uses these purported "discounts" (actually gifts of free goods – which result in higher profits for the hospitals) as leverage to induce the hospitals to buy more of Defendant's products, regardless of whether another surgical ablation product (or a procedure other than surgical ablation) would have been more appropriate. Thus, these market-share commitments interfere with the discretion of the physicians to use the treatment that is in the best interest of each particular patient.

4. Defendant Coaches Hospitals To Upcode and Overcharge Medicare for Closed-Chest, Stand-alone Procedures

121. Starting in approximately 2003, Defendant's sales and marketing departments trained their sales representatives to market their closed-chest, stand-alone, minimally invasive procedure by advising hospitals that they could obtain an over-reimbursement by billing Medicare with a DRG and procedure code for open-heart surgery.

122. Specifically, Defendants' managers trained the Relator and numerous other typical sales representatives to base their marketing pitch on the fact that hospitals could make great profit by over-billing Medicare. The sales representatives were told to explain to hospitals that profit cold be derived by billing Medicare for closed-chest, stand-alone procedures using DRG 108 (procedure code 37.33), which is a code for open-heart surgery.

123. DRG 108 and procedure code 37.33 are incorrect codes to use for closed-chest procedures.

124. ICD-9 procedure code 37.33 designates the use of "open chest" approaches, including the Maze procedure. Defendant's surgical ablation system, used as a stand-alone procedure, does not involve an open approach, and is in fact a minimally invasive closed-chest approach. Defendant instructs hospitals to designate treatment of atrial fibrillation with their product under ICD-9 procedure code 37.33 (excision or destruction of other lesion or tissue of heart, open approach).

125. Because Defendant's stand-alone procedure is closed-chest, the hospital expenses associated with the procedure are significantly less than the hospital expenses for open-heart surgery.

126. The DRG code associated with procedure code 37.33, the code for open-heart surgery, is DRG 108, which reimburses hospitals $30,289. The average length of hospital stay for patients who require procedures that qualify under DRG 108 is seven to twelve days. Correspondingly, the average hospital cost for patients who require procedures that qualify under DRG 108 is $31,074. In contrast, Defendant's closed-chest, stand-alone procedure requires hospitalization for an average of only two to three days. Moreover, the average cost of Defendant's closed-chest, stand-alone procedure is only $10,650, approximately one-third of the average cost of procedures billed under DRG 108.

127. By promoting and encouraging the use of procedure code 37.33, which is designated for open-heart surgery, Defendant coached hospitals to obtain an over-reimbursement of nearly $20,000, or 300% higher than the hospital cost of the procedure, each time Defendant's surgical ablation system is used as a stand-alone procedure.

128. Because there is no specific procedure code that provides reimbursement for the minimally invasive, closed-chest surgical ablation procedure, which is still considered an experimental and investigational procedure, a more appropriate code for the procedure would be procedure code 37.99 (other operations on heart and pericardium). Procedure code 37.99 is assigned

to DRG 111 (Major Cardiovascular Procedures without Complications and Comorbidities) and DRG 110 (Major Cardiovascular Procedures With Complications and Comorbidities). DRG 111 would be the more appropriate of the two DRG codes for purposes of coding Defendant's stand-alone, minimally invasive procedure, because the average length of hospital stay under DRG 111 is 3.43 days, whereas, the average length of hospital stay under DRG 110 is 8.4 days. The average Medicare reimbursement under DRG 111 is $12, 954, which corresponds more closely with the hospital costs of Defendant's minimally invasive, closed-chest procedure.

129. Defendant's promotional materials provide a case study of the exceedingly over-priced reimbursement that a hospital stands to receive from Medicare by designating the codes, DRG 108 and procedure code 37.33, for the use of surgical ablation as a stand-alone procedure. Defendant's sales representatives were instructed that they should promote

130. Defendant's surgical ablation system to treat atrial fibrillation by advising hospitals and doctors that if they used procedure code 37.33 and DRG 108 for the use of Defendant's product as a stand-alone procedure, they could obtain higher reimbursements from Medicare.

5. Specific Cases Of Fraudulent Claims Submitted To Medicare For The Off-Label Treatment Of Atrial Fibrillation

131. Estech issued a September 2005 press release promoting Dr. Gary Allen as a cardiac surgeon who uses "innovative new minimally invasive technique for treating Atrial Fibrillation." The Estech press release promotes the use of its procedure for the off-label treatment of atrial fibrillation, and Dr. Allen is quoted in the press release as stating that he's "comfortable in making…minimally invasive technique available to patients with only AF."

132. During the period from August 1, 2006 through December 31, 2006, Dr. Gary Allen treated patients with atrial fibrillation at Osceola Regional Medical Center, in Kissimmee, Florida. Dr. Allen administered Defendant's Cobra Surgical Ablation System as a closed-chest, stand-alone

procedure to treat patients with atrial fibrillation. Defendant's Sales Representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

133. Upon completion of the procedure, Osceola Regional Medical Center filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive a reimbursement of approximately $30,000 for each stand-alone, closed-chest use of Defendant's Cobra Ablation System.

134. Dr. Robert Lazzara is featured as an innovative surgeon in two Estech press releases-one issued in May, 2006 and the other May 2007. In the Estech press releases, Mr. Lazarra promotes Estech's minimally invasive closed-chest off-label procedures for the treatment of atrial fibrillation.

135. During the period from August 1, 2006 through December 31, 2006, Dr. Robert Lazzara treated patients at St. Joseph Hospital in Tampa, Florida. Dr. Lazzara administered Defendant's Cobra Surgical Ablation System as a stand-alone, closed-chest procedure to treat patients with Atrial Fibrillation. Defendant's Sales Representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

136. Upon completion of the procedure, St. Joseph Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive reimbursements of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

137. During the period from August 1, 2006 through December 31, 2006, Dr. Kevin Accola treated patients at Florida Hospital Kissimmee in Kissimmee, Florida. Dr. Accola administered Defendant's RF Surgical Ablation System as a stand-alone procedure to treat patients

with atrial fibrillation. Defendant's sales representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

138. Upon completion of the procedure, Florida Hospital Kissimmee filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive a reimbursement of approximately $30,000 for each stand-alone, closed-chest use of Defendants' RF Ablation System.

139. During the period from August 1, 2006 through December 31, 2006, Dr. Brian Hummel, Dr. Michael Metke, and Dr. Brandy Puss treated patients at Health Park Medical Center and Southwest Regional Medical Center, in Ft. Myers, Florida. The surgeons administered Defendant's Cobra Surgical Ablation System as a stand-alone, closed-chest, minimally invasive procedure to treat patients with Atrial Fibrillation. Defendant's Sales Representatives were present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

140. Upon completion of the procedure, Health Park Medical Center and Southwest Regional Medical Center filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive reimbursements of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

141. During the period from August 1, 2006 through December 31, 2006, Dr. Clifton Lewis treated patients at Sarasota Memorial Hospital in Sarasota, Florida. Dr. Lewis administered Defendant's Cobra RF Surgical Ablation System as a stand-alone procedure to treat patients with Atrial Fibrillation. Defendant's Sales Representative was present during the procedure to observe the use of the Defendant's RF Surgical Ablation Procedure.

142. Upon completion of the procedure, Sarasota Memorial Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive reimbursements of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

143. During the period from August 1, 2006 through December 31, 2006, Dr. Harold Probaie treated patients at Blake Medical Center and Manatee Memorial Hospital in Bradenton, Florida. Dr. Probaie administered Defendant's RF Surgical Ablation System as a stand-alone procedure to treat patients with Atrial Fibrillation. Defendant's Sales Representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

144. Upon completion of the procedure, Blake Medical Center, and Manatee Memorial Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive reimbursements of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

145. During the period from August 1, 2006 through December 31, 2006, Dr. Jim Obney treated patients at James A. Haley Veterans Hospital in Tampa, Florida. Dr. Obney administered Estech's Cobra Surgical Ablation System as a stand-alone procedure to treat patients with atrial fibrillation. Defendant's sales representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System.

146. Upon completion of the procedure, James A. Haley Veterans Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals

to receive reimbursements of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

147. During the period from August 1, 2006 through December 31, 2006, Dr. Dennis Stapleton treated patients at Naples Community Hospital in Naples, Florida. Dr. Stapleton administered Defendant's Cobra Surgical Ablation System as a stand-alone procedure to treat patients with atrial fibrillation. Defendant's Sales Representative was present during the procedures to observe the use of the Defendant's Cobra Surgical Ablation System.

148. Upon completion of the procedure, Naples Community Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive a reimbursement of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

149. Estech promoted and publicized in a September 2005 press release, Dr. David Jayakar, Chief of Cardiac Surgery at St. Catherine Hospital in East Chicago, Indiana, had successfully completed the first minimally invasive cardiac ablation procedure ever performed using Estech's Cobra Adhere Ablation Catheter System. During the period from August 1, 2006 through December 31, 2006, Dr. Jayakar administered Defendant's Cobra Surgical Ablation System at St. Catherine Hospital as a stand-alone procedure to treat patients with atrial fibrillation. Defendant's sales representative was present during the procedures to observe the use of the Defendant's Cobra Surgical Ablation System.

150. Upon completion of the procedure, St. Catherine's Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospitals to receive

a reimbursement of approximately $30,000 for each stand-alone use of Defendants' RF Ablation System, which is a minimally invasive procedure.

151. Based upon information and belief, Defendant is carrying out similar fraudulent activities in the Southern District of Texas because it employs sales representatives, conducts sales and promotions of its product and facilitates trainings for the off-label use of its procedure in this district.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)-(2), (7)

152. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-151.

153. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729 et seq.

154. As described above, Defendant has, through its off-label marketing campaign and the use of illegal kickbacks, caused physicians and hospitals to perform an increased number of costly inpatient surgical ablation procedures in cases where less costly and less invasive treatments would otherwise have been performed.

155. Through the acts described above, Defendant knowingly presented and caused to be presented to the United States fraudulent claims, records, and statements in order to obtain reimbursement for surgical ablation services performed with Defendant's surgical ablation products.

156. Through the acts described above, Defendant knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for surgical ablation services performed with Defendant's surgical ablation products.

157. The United States, unaware of the falsity or fraudulence of the statements, records, or claims made or submitted by Defendant, its agents, and employees, approved, paid, and continues to

approve and pay claims that otherwise would not have been approved or paid, and has not recovered funds that would otherwise have been recovered.

158. Through the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government in order to obtain government reimbursement for health care services provided under Medicare.

159. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

Prayer

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

1. that Defendant cease and desist from violating 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and Plaintiff recover such other and further relief as the Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury.

Dated: August 21, 2007 Respectfully submitted:

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